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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,868	12/09/2003	Ruchika Singhal	1023-330US01	6697
28863	7590	06/05/2007		
SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			EXAMINER MATTHEWS, WILLIAM H	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 06/05/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/731,868

Applicant(s)

SINGHAL ET AL.

Examiner

William H. Matthews (Howie)

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) 13 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 1-30-07, 10-18-06, 11-3-06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 3-5-07 have been fully considered but they are not persuasive.

With regard to claim 1, Applicant states Berang Patent and Berang Publication lack 1)creating a pocket between scalp and skull adjacent to a scalp fold, and 2)placing at least a substantial portion of the device in the pocket. Examiner disagrees because a pocket is formed by each of the references. Figure 3 of each Berang reference show a S-shaped incision. As shown in Applicant's figure 4, the pocket 30 is the cavity formed for the implant behind the incision. Each of Berang disclose forming such a pocket behind the incision for placement of the implant. The fold is located behind the flap as shown in Figure 3 extending between the ends of incision 34.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12,15-17,24-27,29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 recites "placing a

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substantial portion”, claims 12 and 27 each recite a new combination of placing a device in a pocket and a recess, claims 25,26,29 each recite “placing all of”. These limitations were not described in the specification as originally filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3,5-10,12,15-17,25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. US PN 6,648,914.

Berrang et al. discloses in figures 1-3 and line 42 of col. 9 through line 25 of col. 14 a method of implanting an implantable medical device using local anesthetic comprising creating a pocket (adjacent to a fold) and recess (lines 1-18 of column 10) in the scalp for the implant which comprises a periphery having an angle of approximately 135 degrees, leads, bone screw anchors, first and second module within housings partially covered by a flexible overmold, wherein the maximum thickness is between 4-8mm. Lines 52-59 of col. 14 describe drilling a hole for a lead.

Figure 3 show an S-shaped incision and a pocket created right of the S-shaped incision, and adjacent a fold, in which all of the implant (as best understood by Applicant's specification) is placed into.

Claims 1-4,7,15,25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Berrang et al. US PUB2003/0109903.

Berrang et al. discloses in figures 1, 3 and 25 and paragraphs 46-48,54-56, and 80 a method of implanting an implantable medical device comprising creating a pocket in the scalp for the implant which comprises leads, first and second module within housings partially covered by a flexible overmold, wherein the maximum thickness is approximately 6mm.

Figure 3 show an S-shaped incision and a pocket created right of the S-shaped incision, and adjacent a fold, in which all of the implant (as best understood by Applicant's specification) is placed into.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang et al. US PN 6,648,914 or Berrang et al. US PUB 2003/0109903.

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Each of Berrang et al. '914 and '903 independently meet the limitations of claim 11 but lack the express written disclosure of suturing the flap over the implant to complete the implantation procedure. The Examiner hereby takes Official Notice that suturing a skin flap to complete a surgical procedure is well known in the art.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include the step of suturing the flap to close the incision.

Claims 24,28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang et al. US PN 6,648,914 or Berrang et al. US PUB 2003/0109903.

Each of Berrang et al. '914 and '903 independently meet the limitations of claims 24 and 28-29, as described in the 102 rejections above, but each lack the express written disclosure of implanting the device at the top of the head. Berrang '914 (which is incorporated by reference in '903 at paragraph 0004) disclose the device is preferably located on the head as shown in figure 3 (column 13 lines 35-53), but also describe an unaesthetic visible bump (lines 1-4 of col. 10) of the devices and a desire to improve aesthetics (column 2, lines 36-40). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the placement of the device to a position at the top of the head to eliminate the unaesthetic bump which would be noticeable behind a patient's ear.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

William H. Matthews (Howie)
Examiner
Art Unit 3738



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